

Exhibit D

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION**

IN RE: ETHICON, INC.
PELVIC REPAIR SYSTEM PRODUCTS
LIABILITY LITIGATION

MDL No.: 2327

THIS DOCUMENT RELATES TO:
REBECCA DIANNE PAYNE
Civil Action No.: 2:16-cv-02833

**RULE 26 CASE SPECIFIC EXPERT
REPORT OF KONSTANTIN WALMSLEY, M.D.**

I am Dr. Konstantin Walmsley. Any medical opinions rendered in this report represent my opinions, all held to a reasonable degree of medical certainty, and are based on a reasonable medical probability and scientifically reliable evidence. All opinions are based upon my personal knowledge, as well as my review of the pertinent medical records, my education, training, skill, experience as a physician, and review of the pertinent medical literature.

I. QUALIFICATIONS

I am a licensed physician in the State of New Jersey and a board-certified urologist. I am familiar with the evaluation and treatment of pelvic organ prolapse and stress urinary incontinence. I have implanted transvaginal mesh and am familiar with the properties of these devices and proper implantation technique for these devices. Specifically, I am familiar with Ethicon, Inc.'s ("Ethicon") products, including but not limited to the Prolift and TVT-O products. I have implanted these devices in my patients. I have attended training provided by mesh manufacturers, including Ethicon, regarding these devices. I have reviewed the IFU's for the Ethicon products and reviewed the independent medical literature. Additionally, I have explanted and performed other revision procedures on SUI and POP kits.

In light of my training, knowledge, experience, and qualifications set forth above and in the attached CV, I am familiar with the standards of care applicable in the jurisdiction where the Plaintiff resides as to surgical technique for implantation of the below-referenced Ethicon devices.

Additionally, because of my training, knowledge, experience, and qualifications as set forth above and in the attached CV, I am familiar with the medical complications that are generally associated with mesh repair surgery, and I am experienced in the recognition, diagnosis and treatment of patients suffering from complications caused by pelvic repair mesh implants. The most common complications are pelvic pain, scarring in the vagina and pelvic floor, pain into the legs and thighs, dyspareunia, chronic inflammation of tissue, scar bands or scar plates in the vagina, vaginal shortening or stenosis, erosion, exposure or protrusion of mesh into and through tissues or organs, voiding dysfunction relating to pelvic floor scarring (de novo urinary urgency, urge incontinence, incomplete emptying, and urinary retention), and nerve entrapment. In diagnosing and treating patients with mesh related complications, I often determine the cause of the patients' complications based upon an interview with the patient, a review of her medical records, and knowledge of her prior medical history.

A copy of my CV is attached as Exhibit "A", and a copy of my testimony for the last four years and Fee Schedule is attached as Exhibit "B". The documents I relied upon for this report are contained in Exhibit "C" as well as those documents cited throughout this report.

II. SUMMARY OF CASE SPECIFIC OPINIONS

In formulating my opinions and preparing this report, I reviewed scientific literature, corporate documents from Ethicon, Inc., ("Ethicon"), sample products and depositions

of Ethicon employees and witnesses. The corporate documents, sample products, and depositions were supplied to me by counsel. A list of general materials relied upon and incorporated herein by reference is found within my General Report for these products. Other materials relied upon for this report are listed in Exhibit "C." I have also relied on general causation reports for other Ethicon products. I have reviewed all available medical records in this case. All opinions I have are to a reasonable degree of medical and scientific certainty. I understand that discovery is still ongoing in this case, and I reserve my right to amend my opinions if further information is provided in any form including, but not limited to, corporate documents, depositions, and the expert reports of both Plaintiff and Defense experts. In formulating my opinions herein, I also relied upon my clinical experience in treating stress urinary incontinence.

It is my opinion, to a reasonable degree of medical and scientific certainty, that debilitating injuries Ms. Payne suffered, some of which are discussed below, and the majority of her post-implant medical course are a direct result of implanting the Ethicon Prolift and TVT devices. As discussed in my general liability report, the mesh products, including Prolift and TVT, are not suitable for its intended application as a permanent prosthetic implant for the treatment of stress urinary incontinence and pelvic organ prolapse because of the following characteristics: (a) degradation of the mesh; (b) chronic inflammation and chronic foreign body reaction; (c) mesh product that was never intended to be implanted inside the pelvic cavity and are incompatible with the naturally occurring conditions of the vagina including peroxides and bacteria; (d) deformation, rigidity, fraying, roping, cording, and curling of the mesh products; (e) loss of pore size with tension; (f) fibrotic bridging leading to scar plate formation and mesh encapsulation; (g) shrinkage/contraction of the encapsulated mesh; (h) the difficulty and/or

impossibility of removing the device; and (i) the difficulty of removal of this product means that complete resolution of the patient's complications, including pain, is less likely to occur.

As a result, these mesh devices are not suitable for its intended application as a permanent prosthetic implant for pelvic floor repair in women, such as Ms. Payne, and Ethicon failed to act as a reasonable and prudent medical device manufacturer by manufacturing and selling its polypropylene mesh products in permanent implants like their Prolift and TVT devices. As a result of these and other inadequacies, it is my opinion to a reasonable degree of medical certainty that the implantation of the Prolift and TVT devices caused Ms. Payne to suffer numerous injuries which are permanent in nature. These injuries include: continued and worsening incontinence, difficulty voiding, voiding dysfunction, nocturia, urinary stream abnormality, urgency and frequency, dyspareunia, mesh erosion and extrusion into urethra and bladder, infection, pelvic and vaginal pain, extensive scarring, painful bowel issues, and vesicovaginal fistula.

The medical treatment required to treat Ms. Payne's injuries caused by both mesh devices was a foreseeable result of her complications. In formulating my opinions and preparing this report, I considered the scientific literature, corporate documents from Ethicon, and case-specific materials such as medical records and deposition testimony. I further considered my own clinical experience in treating stress urinary incontinence in my practice. The corporate documents were provided to me by counsel. I have also relied upon the Ethicon TVT-Obturator General Causation report authored by Dr. Brue Rosenzweig, the Prolift General Causation Report authored by Dr. Abbas Shobeiri, and the Gynecare Prolift General Causation Report authored by Dr. Donald Ostergard in the MDL. All opinions I have offered are held to a reasonable degree of medical and scientific certainty.

III. CASE HISTORY AND REPORT

Throughout my analysis of Ms. Payne's conditions, I have relied upon her medical records and medical history to date. Her medical history is outlined as follows:

Ms. Payne was 57 at the time of her pelvic mesh implant. She was a G2 P2. She delivered two children through live vaginal births. Her past medical history was remarkable for stress urinary incontinence, vaginal vault prolapse, symptomatic distal rectocele, fistula, cystocele, perineocele, intrinsic sphincter deficiency, mild genital atrophy, obstructive sleep apnea, GERD and hypertension. Her past surgical history was remarkable for partial vaginal hysterectomy, cholecystectomy, vaginal vault suspension, uterine repair, hernia repair, knee surgery, hemorrhoidectomy, transvaginal sling and mesh explant after erosion into urethra and bladder, urethrolisis, repair of cystourethrocele, Kelly plication, cystocele repair, enterocele repair, transurethral injection of collagen, and retropubic autologous rectus fascia pubourethral sling with removal of abdominal rectus fascial strip. She never smoked tobacco products.

On September 10, 2007, Ms. Payne was admitted to Brookwood Medical Center for implantation of two mesh implant devices. Her chief complaint was vaginal vault prolapse and stress urinary incontinence. Dr. David Gams identified both her preoperative diagnosis and postoperative diagnosis as vaginal vault prolapse, stress urinary incontinence, cystocele and rectocele. Dr. David Gams performed a sacrospinous vault suspension, a suburethral sling placement, uterine repair with mesh, and posterior repair with mesh. Dr. Gams used TVT and Prolift mesh products in the surgical procedure.

On February 5, 2009, Ms. Payne visited Dr. Edward Varner at the University of Alabama Birmingham Hospital clinic for severe mixed incontinence with stress, urge, and unconscious

incontinence, voiding dysfunction, and fecal incontinence. Dr. Varner prescribed Estrace cream and recommended she proceed with urodynamics.

On April 23, 2009, Ms. Payne underwent urodynamics testing with Dr. Varner at The Kirklin clinic. Her test results showed leakage after coughing and urethral incompetence. He diagnosed her with severe mixed incontinence, voiding dysfunction including unconscious leakage, symptomatic distal rectocele post previous posterior Prolift procedure and mild genital atrophy. Dr. Varner planned to proceed with bulking agent Collagen injections later that month.

On May 22, 2009, Ms. Payne visited Dr. Varner at The Kirklin Clinic for Transurethral injection of Collagen. Dr. Varner noted that her rectocele symptoms were better. He stated she experienced mixed urinary incontinence with significant ISD, plus he observed she had a perineocele.

On August 7, 2015, Ms. Payne was scheduled for sling removal, removal of anterior and posterior vaginal mesh, cystocele repair, enterocele repair, and rectocele repair at the North Georgia Medical Center by Dr. Michael Hulse. The reason for mesh removal related to it causing dyspareunia, voiding dysfunction, dysuria, nocturia, incontinence including urgency, frequency and retention, pelvic pain in the suprapubic and vaginal regions, with mesh erosion attributed to the mesh devices. At the time of her mesh excision, her preoperative diagnosis included the following: foreign body in the genitourinary tract with an anterior and posterior Prolift mesh as well as Ethicon TVT sling; pelvic pain; dyspareunia; urinary frequency; urinary stream abnormality; painful bowel movements; urge incontinence; and stress incontinence. Her postoperative diagnosis included those above and additionally erosion of the sling into the urethra and erosion of the anterior mesh into the bladder. Dr. Hulse's procedure included urethrolisis, sling removal, repair of urethral erosion site, removal of anterior mesh, repair of

bladder erosion site, removal of posterior mesh, anterior and posterior repair, posterior enterocele repair and cystoscopy. The procedure was performed without complications. The operative note states that the mesh was pulling very tightly into the rectum, but had not yet eroded into the rectum. Further, the mesh was split up the midline all the way to the apex and then split into two pieces. Each support arm had to be isolated, transected and removed. Dr. Hulse requested that an intravenous pyelogram be performed because of indications of back pain to determine if the patient's ureter was blocked. No obstructive uropathy was detected.

On December 21, 2015, Ms. Payne was admitted to UAB Hospital for Retropubic autologous rectus fascia pubourethral sling with removal of abdominal rectus fascial strip by Dr. Varner. The operative note stated that Ms. Payne had a previous failed mesh implant and removal. The prior treatment of Collagen bulking injections failed, and there was extensive scarring below the urethral with low blood supply. Urodynamics testing revealed significant stress incontinence with intrinsic sphincter deficiency.

On April 4, 2016, Ms. Payne was admitted to UAB Hospital for repair of a vesicovaginal fistula at the bladder neck area by Dr. Varner for vaginal mesh complications from her procedures performed elsewhere. Dr. Varner did a transvaginal dissection and repair of the vesicovaginal fistula without complications under general anesthesia followed by cystoscopy.

IV. CASE SPECIFIC EXPERT OPINIONS

Ms. Payne was implanted with Ethicon's Prolift and TVT-Obturator devices on September 10, 2007, and both the TVT-Obturator and the Prolift significantly caused her injuries. Ms. Payne should not have been implanted with the Ethicon Prolift and TVT pelvic mesh because the poor design of the devices increased the risk of serious complications and caused her specific complications. These complications include, but are not limited to continued

and worsening incontinence, difficulty voiding, voiding dysfunction, nocturia, urinary stream abnormality, urgency and frequency, dyspareunia, mesh erosion and extrusion into urethra and bladder, infection, pelvic and vaginal pain, extensive scarring, painful bowel issues, and vesicovaginal fistula. Ms. Payne may need additional surgeries in the future due to mesh erosion and exposure or other complications.

Based on my background, education, training, and experience, as well as the medical records and deposition testimony offered in this case, it is my opinion that Dr. David Gams' and Dr. Michael Hulse's treatment of Ms. Payne met the standard of care. The pre-operative evaluation of the patient met the standard of care. The mesh implant procedures were recommended due to complaints of urinary incontinence symptoms and pelvic organ prolapse, and was performed within the standard of care with no evidence of surgeon error or deviation from the procedural steps enumerated in the IFU.

In determining the cause of a specific injury, it is necessary to "rule in" potential causes of the injury and then, by process of elimination, "rule out" the least likely causes to arrive at the most likely cause. This process is known as differential diagnosis or differential etiology and it is a well-established and universally accepted methodology for determining the cause of injuries employed by physicians throughout the United States. I have used that methodology in arriving at my opinions in this case. In general, my expert opinions can be summarized as follows:

A. The polypropylene mesh used in Ethicon's Prolift and TVT devices is not suitable for its intended application as a permanent prosthetic implant for stress urinary incontinence and pelvic organ prolapse because the pores are too small, it is a heavy weight mesh, it degrades over time, causes chronic foreign body reactions, fibrotic bridging, mesh contracture/shrinkage,

fraying, particle loss, biofilm formation and infections, has sharp edges, ropes, curls, and deforms, and the pores collapse with tension;

B. Ethicon's mesh is not suitable for its intended application as a permanent prosthetic implant for stress urinary incontinence and pelvic organ prolapse due to the lack of adequate studies supporting its safety and efficacy. In addition, it is not suitable for its intended application because Ethicon did not consider relevant and knowable problems and complications associated with implanting its products through the vagina and into the pelvic cavity;

C. Many of Ethicon's claims to the public, including physicians, patients, and through marketing materials, concerning the properties and safety of its mesh products are not supported by the available medical and scientific literature;

D. Ethicon's prior experience with the Protegen device was disregarded by Ethicon when developing its other products including the Prolift and TVT products;

E. Ethicon's warnings and disclosures of adverse events, risks, and characteristics of the product in its Prolift Directions for Use ("DFU"), do not fully or adequately disclose the known and knowable adverse reactions and risks associated with this product. Ethicon did not disclose information to physicians in their DFU regarding characteristics of their products that make them unsuitable for their intended application as a permanent prosthetic implants for pelvic floor repair; this includes: small pore size; heavy weight mesh; the meshes' tendency to degrade over time, cause chronic foreign body reactions, fibrotic bridging, contract, shrink, fray, lose particles, rope, curl, or deform; the pores collapse with tension; the meshes become difficult or impossible to remove; the meshes tested positive for cytotoxicity; and, the MSDSs state that they are incompatible with strong oxidizers, such as peroxides;

F. The benefits of the Prolift and TVT products are outweighed by the severe, debilitating, and life changing complications associated with these devices;

G. Non-mesh interventions for stress urinary incontinence and pelvic organ prolapse are effective and produce less severe, debilitating, and life changing complications than the Prolift and TVT devices;

H. Ethicon knew that its TVT-Obturator and Prolift mesh devices were not appropriate for use, but it failed to modify/change the mesh to a larger pore size or a lighter weight mesh that would be less likely to degrade, cause excessive foreign body reactions or chronic inflammation, or deform, become rigid, fray, rope, or cord after implantation, and cause the formation of fibrotic bridging that leads to scar plate formation and mesh encapsulation, which makes these devices difficult if not impossible to remove. According to Ethicon's internal documents, it was unwilling to change the mesh because of its economic interest in maintaining its competitive advantage in the market and, therefore, Ethicon put profits before patient safety.

I. Ethicon's design of the Prolift and TVT devices was flawed because it cannot adequately describe, inform, or explain to physicians how to properly "tension" the devices. Further, the devices shrink, contract, rope, and curl making it difficult or impossible to tension in a safe manner for patients;

J. Ethicon's products are not suitable for permanent implant because the Material Safety Data Sheets ("MSDS") for polypropylene resin used to manufacture polypropylene states that polypropylene is incompatible with strong oxidizers, such as peroxides which are readily found in the vagina;

K. Ethicon's mesh products are also not suitable for permanent implant because the toxicity testing of the polypropylene mesh revealed that it was cytotoxic which can cause cell death and complications;

L. The design of the devices is flawed because it is not designed for special patient populations; nor do the DFUs nor marketing documents inform physicians that certain patients will have poorer outcomes and higher risks;

M. Ethicon failed to reveal material facts about complication and conflicts of interest regarding key studies in key marketing documents;

N. As a result of the defects in the Prolift and TVT devices, Ms. Payne suffered and continues to suffer life-long permanent injuries; and

O. Based on my review of the medical records, there is no evidence that any of Ms. Payne's doctors deviated from the standard of care in their treatment of her. There is no evidence that any improper medical care caused or contributed to cause Ms. Payne's injuries. After the implant of the Ethicon mesh devices, Ms. Payne developed and experienced continued and worsening incontinence, difficulty voiding, voiding dysfunction, nocturia, urinary stream abnormality, urgency and frequency, dyspareunia, mesh erosion and extrusion into urethra and bladder, infection, pelvic and vaginal pain, extensive scarring, painful bowel issues, and vesicovaginal fistula.

To a reasonable degree of medical certainty, the small pore size, the heavy weight mesh, degradation over time, chronic foreign body reactions, fibrotic bridging, mesh contracture and shrinkage, fraying, particle loss, biofilm formation and infections, sharp edges, roping, curling and deformation, and the pore collapsing with tension of the mesh devices implanted caused and contributed to an exacerbation of these symptoms.

It is my opinion that Ms. Payne will continue to suffer from long term risks of future erosion/exposure, continued and worsening incontinence, difficulty voiding, voiding dysfunction, nocturia, urinary stream abnormality, urgency and frequency, dyspareunia, mesh erosion and extrusion into urethra and bladder, infection, pelvic and vaginal pain, extensive scarring, painful bowel issues, and risk of recurrent vesicovaginal fistula.

She will likely also continue to experience chronic foreign body reaction and chronic inflammation. She will have the possibility of future risks and symptoms as long as there is mesh material left in her body. As a result, Ms. Payne may need additional surgeries to remove the remaining Ethicon mesh products, and treat vaginal scarring, pelvic pain, recurrent infections, and other injuries associated with the original implantation of the devices. Ms. Payne will likely require pelvic floor therapy and physical therapy to alleviate her symptoms which stem from the implant of both devices. To a reasonable degree of medical certainty, the Prolift and TVT mesh implants and their effect on the surrounding tissues are the cause of Ms. Payne's injuries.

This is consistent with my experience and full clinical picture of mesh related complications. It is my opinion to a reasonable degree of medical certainty that Ms. Payne will have continued and ongoing complications and need additional medical treatments in the future related to these permanent complications she has suffered and will continue to suffer from the inadequacies of the Prolift and TVT devices.

Based on my review of the entire body of literature, my experience, review of Ms. Payne's medical records and deposition, it is my opinion, to a reasonable degree of medical certainty, the Prolift and TVT devices, and their effects on the surrounding tissues have caused, contributed to cause, and exacerbated Ms. Payne's symptoms. But for the Prolift and TVT

devices implantation, Ms. Payne would not experience her current symptoms to the extent they currently exist.

I considered Ms. Payne's medical history in my evaluation. Her past medical and surgical history is stated in detail above. I have ruled out other procedures and conditions as the causes of Ms. Payne's complaints and damages. None of her previous medical conditions and procedures caused or exacerbated her symptoms as they currently exist today. To a reasonable degree of medical certainty, there are no other reasonable causes for her symptoms given Ms. Payne's medical and surgical history. Temporally, her symptoms were caused, contributed to be caused and exacerbated by the Prolift and TVT devices.

Based on my background, education, training, and experience, it is my opinion that Dr. David Gans' and Dr. Michael Hulse's treatment of Ms. Payne met the standard of care. The procedures were performed within the standard of care with no evidence of surgeon error or deviation from the procedural steps. There was no evidence of any mesh device related surgical complications, excess surgical duration, or surgical site contamination in the records.

I highly recommend that Ms. Payne be followed up with a continuum of care, including but not limited to, pelvic floor physical therapy, counseling, biofeedback therapy, and/or Botox therapy for her continued symptoms, which may or may not be ultimately successful. This continuum of care is time-consuming, socially disruptive, very expensive, and not usually covered by insurance.

It is also my opinion that there were reasonably feasible alternatives available to Ethicon's mesh devices and for the treatment of Ms. Payne. Safer alternative designs, rather than the Prolift and TVT polypropylene mesh products, existed for this patient. I have experience with many of these safer alternative designs, and based on my experience and review of medical

literature and other materials, it is my opinion that these alternative designs were safer and feasible for Ms. Payne. These safer alternative designs include:

- (1) the use of sutures, including delayed absorbable sutures like PDS, in a colposuspension procedure like the Burch and native tissue repair for POP repair;
- (2) autologous fascia sling;
- (3) an allograft sling or POP repair such as certain biological graft materials; and,
- (4) a sling or POP repair with less polypropylene such as Ultrapro.

These safer alternative designs were capable of preventing Ms. Payne's injuries and damages, as I have described in my report, that were a result of the specific design flaws of the Prolift and TVT polypropylene, including degradation, cytotoxicity, stiffness, migration, deformation, fraying, roping, cording, curling, banding, scarring, shrinkage/contraction, scar plate formation, chronic inflammation, chronic foreign body reaction, loss of pore size with tension, dense, heavy, and frayed, rough edges. If any of these safer alternative designs been used for Ms. Payne, she would not have suffered the injuries I set forth in my report, as her injuries were caused by the specific design flaws of the Prolift and TVT mesh devices discussed above and in my general report. The likelihood that the design of the Prolift and TVT would cause Ms. Payne's injuries and damages, and the gravity of those injuries and damages outweighed the burden on Ethicon of adopting such alternative designs and the adverse effects, if any, of such alternative designs on the utility of the Prolift and TVT products. The inadequate warnings about the Prolift and TVT significantly increased the likelihood of injuries and damages to Ms. Payne, caused or contributed to cause the permanent injuries and damages to Ms. Payne, and Ethicon failed to use reasonable care to provide adequate warnings to users and handlers of the Prolift and TVT products, as discussed herein.

Also, as discussed in the general reports, Ethicon failed to include and/or describe the significant adverse events and risks in their DFU for these devices. Ethicon did not fully inform physicians about numerous adverse reactions/risks associated with the Prolift and TVT despite the fact that Ethicon had scientific knowledge of the risks from the time the product was first sold. As a result, physicians were unable to fully consent and inform patients of the risk associated with the Prolift and TVT. In addition, some risks included by Ethicon in the DFU are mischaracterized to minimize the actual risks. Finally, when given numerous opportunities to update the DFU, and in the face of specific requests to do so from numerous medical professionals, Ethicon did not make the necessary updates.

To a reasonable degree of medical certainty, this prevented physicians and patients the ability to make an informed choice regarding the use of the Prolift and TVT. For a surgeon to properly inform the patient of all the known risks included in any procedure involving an implantable medical device, the surgeon relies upon the manufacturer to have scientific knowledge of and convey all characteristics of its products that could impact safety and efficacy. Specifically, surgeons rely on the “Adverse Events/Risks” section of a medical device DFU to gain scientific knowledge regarding adverse events or undesirable effects that the company knows are associated with these products.

For these reasons, and as fully outlined in the general expert reports, Ethicon failed to advise Ms. Payne’s implanting physician of the adverse events and risks associated with the Prolift and TVT. Dr. Gams consented Ms. Payne for the procedure, but according to the DFU, he could not have properly consented her because he was not fully aware given the inadequate DFU information. Ms. Payne’s implanting physician, Dr. Gams, did not know about many of these risks before he implanted Ms. Payne with these devices. Ethicon had knowledge of these

risks and, therefore, it should have included them in the DFU so that Dr. Gams could perform an appropriate risk-benefit analysis. As a result, to a reasonable degree of medical certainty, it is my opinion Ms. Payne was damaged as a result of injuries she suffered that were not disclosed to her implanting physician by Ethicon.

V. CONCLUSION

To a reasonable degree of medical certainty, it is my opinion that the Ethicon Prolift and TVT mesh devices caused Ms. Payne's conditions including continued and worsening incontinence, difficulty voiding, voiding dysfunction, nocturia, urinary stream abnormality, urgency and frequency, dyspareunia, mesh erosion and extrusion into urethra and bladder, infection, pelvic and vaginal pain, extensive scarring, painful bowel issues, and vesicovaginal fistula.

In addition, it is my opinion to a reasonable degree of medical certainty that she will have continued and ongoing complications and need additional medical treatments in the future, specifically including additional revision surgery, related to the permanent complications she suffered from the inadequacies of the Ethicon Prolift and TVT mesh devices. I reserve the right to amend and/or supplement this report if new discovery or facts necessitate amendment or supplementation.

Dated this August 3rd, 2018.

Sincerely,

A handwritten signature in black ink, appearing to read 'Konstantin Walmsley', with a stylized, cursive script.

Konstantin Walmsley, M.D.

EXHIBIT A

Curriculum Vitae
Konstantin Walmsley, Board Certified in Urology, #14764
November 20, 2015

Address: Urology Group of New Jersey
777 Bloomfield Avenue
Glen Ridge, NJ 07028
(973)725-9096

Date and Place of Birth: April 29, 1970; Philadelphia, PA

Marital Status: Married; one daughter, one son

Education:

1988	Diploma, Collegiate High School for Boys, New York, NY
1992	B.A., Honors in Chemistry, University of Pennsylvania, Philadelphia, PA
1997	M.D., Vanderbilt University Medical College, Nashville, TN

Training and Employment:

Spring 1988	Research Assistant, Dept. of Surgical Metabolism, Memorial Sloan-Kettering Cancer Center, New York, NY Sponsor: Nadarajen Vidylingum, PhD
Fall 1989	Research Assistant, Dept. of Neurosurgery, Graduate Hospital, Philadelphia, PA Sponsor: William J. O'Connor, MD
Summer 1993	Research Fellow, Dept. of Physiology, Diabetes Summer Fellowship, Nashville, TN Sponsor: Alan D. Cherrington, PhD
1993-1994	Anatomy and Problem-Based-Learning Tutor Department of Pathology Vanderbilt University, Nashville, TN
1993-1994	MCAT Instructor Stanley H. Kaplan, Nashville, TN
1995-1996	Howard Hughes Medical Institute—NIH Research Scholar, Laboratory of Tumor Immunology and Biology National Cancer Institute, National Institutes of Health, Bethesda, MD Sponsors: Jeffrey Schlom, PhD
1996-1997	Research Assistant, Dept. of Urology Vanderbilt University Medical College Sponsor: Robert J. Matusik, PhD

6/22/97	Assistant Surgeon
-6/30/98	New York Presbyterian Hospital-Cornell, New York, NY
7/1/98	Clinical Associate in Surgery
-6/30/99	New York Presbyterian Hospital-Cornell, New York, NY
7/1/99	Clinical Associate in Urology
-6/30/03	New York Presbyterian Hospital-Cornell and Memorial Sloan-Kettering Cancer Center, New York, NY
7/1/03-	Clinical Instructor in Female Urology and Voiding Dysfunction
6/30/04	New York Presbyterian Hospital-Columbia, New York, NY Director of Urodynamics and Department of Urology Helen Hayes Hospital, West Haverstraw, NY
8/15/04-	Associate Urologist and Clinical Instructor
10/31/08	Montclair Urological Group, P.A., Glen Ridge, NJ
11/1/08-	Partner, Urology Group of New Jersey,
Present	Glen Ridge, NJ

Fellowships and Awards:

1988	National Merit Scholarship Semifinalist
1992	Phi Lambda Upsilon Member (Chemistry Honors Society)
1991	Quarterfinalist, Henley Royal Regatta
1992	Silver Medalist, Lightweight Varsity National Rowing Championships
1992	B.A. awarded with honors for senior thesis
1993	Diabetes Research Summer Fellowship
1993-1997	Microbiology and Immunology Honors Society
1994-1997	Candy Robinson Scholarship Society
1995-1996	Howard Hughes Medical Institute - NIH Research Scholar
1997	John L. Shapiro Award for Excellence in Pathology
2002	Honorable Mention, Research Section, Ferdinand C. Valentine Urology Residents Essay Contest, New York, NY
2003-2004	Fellow in Female Urology and Voiding Dysfunction Preceptor: Steven A. Kaplan, MD
2006-present	Top Doctor, NJ Monthly Magazine
2007-present	Top Urologist, Consumers' Research Council of America
2009-2010	Vice President, Medical Staff, Mountainside Hospital, Montclair, NJ
2011-2012	President, Medical Staff, Mountainside Hospital, Montclair, NJ
2012-2014	Chairman, Board of Trustees, Hackensack University Medical Center-Mountainside, Montclair, NJ
2013-present	Chairman, Department of Surgery, Hackensack University Medical Center-Mountainside, Montclair, NJ
2013-present	Chairman, Credentialing Committee, Hackensack University Medical Center-Mountainside, Montclair, NJ

Activities:

1979-1984	Metropolitan Opera, Boy Soprano
1989-1992	Men's Varsity Lightweight Crew, University of Pennsylvania
1993-1995	Alcohol and Substance Abuse Program Big Brother, Nashville, TN
1997-2003	Cornell Urology Urinary Track Team, 13 marathons completed (personal record 3:04:59)
2012-2016	Completed five ultramarathons

Abstracts and Presentations:

1. "The Conducting and Thermal Properties of Polyaniline Salts" Walmsley K. Honors Program, Chemistry, University of Pennsylvania, Philadelphia, PA, May 3, 1992
2. "The Vanderbilt Transplant Center: Results Between 1998 and 1993" Pinson CW, Walmsley K, Richie RE, Johnson JE, Frist W, Wolff SW. Poster presentation at the *American College of Surgeons*, San Francisco, CA, Oct. 12-14, 1993.
3. "Evidence that the Brain is Directly Sensitive to Physiologic Levels of Plasma Insulin in Vivo" Walmsley K, Dunham BP, Davis SD, Shavers C, Snead WP, Hastings JR, Cherrington AD. Poster Presentation at the *American Diabetes Association Annual Meeting*, New Orleans, LA, June 11-14, 1994.
4. "Vago-Sympathetic Blockade Decreases Basal Hepatic Glucose Production in the Conscious Dog" Walmsley K, Neal DW, Hastings JR, Cherrington AD. Poster presentation at the *American Diabetes Association Annual Meeting*, Atlanta, GA, June 10-13, 1995.
5. "Generation of Human T-Cell Lines Specific for Prostate Specific Antigen Using an Oligo-Epitope Peptide" Walmsley K, Correale P, Nieroda CN, Zaremba S, Tsang, KY, Schlom J. Podium presentation at the *Proceedings of the American Association of Cancer Research*, Washington, D.C., April 22-25, 1996 and *Class of 1995-1996 Scientific Presentations*, Howard Hughes Medical Institute-National Institutes of Health Research Scholars Program, Bethesda, MD, May 22, 1996.
6. "CEA-Specific Cytotoxic T Cell Immunity in Phase I Clinical Trials Using a Recombinant CEA-Vaccinia Vaccine" Tsang KY, Zhu MZ, Nieroda CN, Correale P, Zaremba S, Walmsley K, Schmitz, J, Hamilton, J. Podium presentation at the *Proceedings of the American Association of Cancer Research*, Washington, D.C., April 22-25, 1996.
7. "The Inheritance of Varicoceles" Walmsley K, Goldstein M. Poster presentation at the Annual Meeting of the *American Urologic Association*, Anaheim, CA, June 12-16, 2001. (an AUA CD-ROM top poster presentation).

8. "Varicocele Management in the Pediatric Patient: Results with Microsurgical Varicocoelectomy" Walmsley K, Coleman J, Kelly C, Goldstein M, Poppas DP. Podium presentation at the Annual Meeting of *American Academy of Pediatrics*, San Francisco, CA, October 16-20, 2001.
9. "Effects of Antibody to Transforming Growth Factor Beta in Unilateral Ureteral Obstruction of Mice Lacking the Gene for Inducible Nitric Oxide Synthase" Walmsley K, Seshun SV, Chen J, Ledbetter S, Vaughan ED, Poppas DP, Felsen D. *Ferdinand C. Valentine Urology Residents Essay Meeting*, New York, NY, March 20, 2002. Poster presentation at the Annual Meeting of the *American Urological Association*, Orlando, FL, May 25-30, 2002 (an AUA CD-ROM top poster presentation).
10. "Urodynamic Classification of Overactive Bladder" Flisser AJ, Walmsley K, and Blaivas JG. Podium presentation at the Annual Meeting of the *American Urological Association*, Orlando, FL, May 25-30, 2002.
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13. "The Diagnosis and Management of BPH." Grand Rounds, Mountainside Hospital, March 8, 2005.
14. "Overactive Bladder and Urinary Incontinence-Treatment Options in the 21st Century." Grand Rounds, Mountainside Hospital, February 6, 2006.
15. "PSA Screening in the 21st Century: The New State of the Art." Grand Rounds, Mountainside Hospital, September 8, 2007.
16. "Updates in the Diagnosis and Treatment of Prostate Enlargement." Grand Rounds, Mountainside Hospital, March 11, 2010.
17. "Hypogonadism: Prevalence, Diagnosis, and Treatment Options." Grand Rounds, Hackensack University Medical Center, April 4, 2013.

Publications:

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EXHIBIT B

Prior Testimonies

2007 – Mucchiolo vs Steckel et al: (Case in which I was a resident assisting on case with subsequent complications)

2010 – Gonzalez v. Ethicon (case of Ethicon stapler resulting in complications)

2011 – Case in long island involving delay in diagnosis of BPH in patient with urinary retention

2012: Henebury vs. Corea (case of a complication following ureteroscopy)

2013: Schubert vs. Roberts (Prolift complication)

2013 Sorezza vs. Scheuch (case of a complication following PCNL)

3/2014 – Martinez vs. AMS

5/2014 – Humphreys vs Crothall Heath Care (case of possible sexual harassment)

7/2014 – Betancourt vs. BSC

7/2014 – Nunez vs. BSC

11/2014 – Ash vs. Bard; Earls vs. Bard

12/2014 - Curtis vs. BSC; Varnadoe vs. BSC; Curtis vs. BSC; Davis vs BSC

11/2015 – Stewart vs. Meshesha

2/2016 – Del Castillo vs. Caso

3/2016 – Ridgley vs. Ethicon; Fox vs. Ethicon

6/2016: Lindberg vs. Ethicon

6/2016: Manor vs. Ethicon; Martin vs. Ethicon; Pridmore vs. Ethicon; Bailey vs. Ethicon

6/2016: Vanbuskirk vs. Ethicon; Barr vs. Ethicon; Javins vs. Ethicon; Garcia vs. Ethicon

7/2016: Birt vs. Shashoua

8/2016: Birt vs. Ethicon; Baker vs. Ethicon; Ward vs. Ethicon; Phillips vs. Ethicon

10/16: Mattingly vs. Ethicon; Berry vs. Ethicon

11/16: Collins vs. Bard

2/17: Ray vs. Ethicon

COMPENSATION FOR MY REVIEW, STUDY, AND TESTIMONY

My fee for review of medical records, corporate documents and other related materials, testimony, and travel time is an hourly rate of \$500.00 per hour.

EXHIBIT C

Case Specific Reliance List
Rebecca Payne
Dr. Konstantin Walmsley, M.D.

Medical Reviewed:

- Dr. M. Suzanne Gilliland – Gadsden Women’s Clinic
- Dr. Michael Hulse
- UAB Medical Center
- North Georgia Medical Center
- Brookwood Medical Center
- Dr. Robert E. Varner

Litigation Documents Reviewed:

- Short Form File Stamped Complaint
- Plaintiff Profile Form
- Plaintiff Fact Sheet

Materials Reviewed

Depositions of Medical Providers

Depositions of Client and Partner (if applicable)

Expert Reports Related to Case

Medical & Billing Records

Instructions for Use

Boston Scientific Corp.’s TVM products Instructions for Use

Boston Scientific Corp.’s TVM products Patient Brochures

Incorporated Materials

All materials cited in and reviewed for the TVT general causation reports

Medical Literature

AMA 8.08

Boston Scientific Corp.’s TVM products Instructions for Use

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